IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Marius HAURI et al.	)	
Serial No:	10/665,514	)	Attorney Docket: 0100/0165
Filed:	September 22, 2003	)	
For:	SAFETY NEEDLE ASSEMBLY AND METHOD FOR MAKING THE SAME	)	Appeal No,

APPELLANT'S BRIEF ON EX PARTE APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a brief for appealing the final rejecting of pending claims 1, 2, 4-6, 8-11, 13-20, 23-25 and 27-28 of the above-identified application.

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FEE AUTHORIZATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached herewith please find form PTO-2038 authorizing the debit of $510.00 for the filing of the accompany Appeal Brief for the above-identified application.

The Commissioner is further hereby authorized to debit funds from Deposit Account No. 50-0501 if the amount noted above is insufficient. A duplicate copy of this letter is attached.

Respectfully submitted,

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717 North Fayette Street
Alexandria, VA 22313
Phone: (703) 299-4090

Date: Jan 16, 2008

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REAL PARTY IN INTEREST

The real party in interest is Smiths Medical ASD, Inc.

The instant invention was originally assigned by the inventors to Portex, Inc. per an assignment recorded September 22, 2003 at the Assignment Branch at the U.S. PTO. The name of Portex, Inc. was subsequently changed to Smiths Medical ASD, Inc. The change of name was submitted to the U.S. PTO on March 9, 2004.

RELATED APPEALS AND INTERFERENCES

As far as is known, there are no pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or having a bearing on the Board's decision in the pending appeal.[1]

[1] Application No. 10/832,339, a CIP of the instant application, was filed on April 27, 2004. So far no Office Action has been received for this case.

STATUS OF CLAIMS

Claims 1, 2, 4-11, 13-21 and 23-28 are pending in this application.

Dependent claims 7 and 26 were deemed allowable.

Claims 3, 12 and 22 were canceled.

Being appealed claims 1, 2, 4-6, 8-11, 13-21, 23-25 and 27-28 (along with allowable claims 7 and 26) are reproduced in the Claims Appendix of this Appeal Brief.

STATUS OF AMENDMENTS

There was no amendment filed subsequent to the final rejection Office Action of August 24, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a safety needle assembly that has its needle sheath attached to a collar that in turn is mounted about the hub of the needle assembly. To achieve this, the at issue safety needle assembly is made up of components that are quite different from those in the prior art. The major components of the instant invention are shown for example in Fig. 1.[2] They include a hub 4, a collar 6 to which a housing 8 is pivotally attached, and a sheath 12.

Of the being appealed claims, claim 1, 11 and 20 are independent.

Claim 1 recites a safety apparatus that comprises a needle (4) having a proximal portion (18) and a distal portion (20), and a needle (22) extending from a distal end (24) of the needle hub (Figs. 1-5, 6, 7) [paragraph 0028]. The safety apparatus also comprises a collar (6) rotatably mounted onto the distal portion of the needle so that the collar is rotatable about the needle hub. There is a first engage mechanism (68) at the inner circumference surface of the collar (Figs. 8 and 9) [0033-0034]. A housing (8) is pivotally connected to the collar [0035]. The safety apparatus further includes a needle sheath (12) having a proximal portion (74) with a second engage mechanism (90) at its outer circumferential surface (Fig. 12) [0038]. The first and second engage mechanisms (68, 90) of the collar and needle sheath, respectively, fit to each other when the sheath is fitted to the collar. The proximal portion (74) of the needle sheath has only one side in contact engagement to the collar for covering the needle extending from the distal end of the needle hub, and the sheath is not in contact with the needle hub when the it is fitted to the collar and the first and second engage mechanisms are engaged to each other (Figs. 4, 5) [0038].

Thus, as best shown in the cross-sectional view of Fig. 4, the safety apparatus of claim 1 has a mechanism 68 at its collar 6 that engages a corresponding mechanism 90 at the sheath 12, so that needle 22 is covered by the sheath 12, which in turn is only in contact with the inner surface of collar 6 and yet at the same time not in contact with extension 24 of the needle hub. Also, given that collar 6 is mounted about needle 4 (set

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[2] For the convenience of the Board, the figures of the instant application are attached to th Drawings Appendix.

forth in more detail in dependent claim 7), collar 6, along with sheath 12, is rotatable about needle hub 4.

Claim 11 is a combination claim that recites a needle hub (4) having a proximal portion (18) and a distal portion (20) that has a luer connector (40) at its proximal portion, and a ring (28) surrounding but in spaced relationship with the luer connector (Figs. 6, 7). There is at least one window (42) provided at the ring to enable the viewing of the luer connector, the ring being graspable by a user to remove the needle hub from the syringe. The distal portion of the needle hub has a distal end from which a needle extends [0029-0030]. There is further a collar (6) having a housing (8) pivotally connected thereto that fits to and rotatable about the distal portion of the needle hub [0032-0033]. The combination moreover includes a needle sheath (12) that has a proximal portion (74) with only one side in contact engagement to the collar, but not in contact with the needle hub. The needle sheath is removable from the collar to expose the needle for use (Figs. 1-10, 12) [0038].

The combination device of claim 11 therefore requires a collar fitted to and rotatable about the needle hub and a needle sheath that is in contact engagement to the collar at only one side and not in contact with the needle hub. In addition, the combination device requires that there be a ring that surrounds but in space relationship with the luer connector of the needle hub, and that there is at least one window provided at the ring to enable the viewing of the luer connector. By allowing the viewing of the luer connector, the user can readily see flashing of blood during a blood withdrawing procedure so as to determine whether the needle has been correctly inserted into the vein of a patient [0030].

Claim 20 is a method claim that is directed to the making of the needle assembly of the instant invention. The method comprises the step of providing a needle hub (4) having a proximal portion (18) and a distal portion (20) [0028], the step of providing a collar (6) with a housing (8) pivotably connected thereto, with the collar having a first engage mechanism (68) formed at its inner circumferential surface [0032-0033], the step of rotatably mounting the collar directly onto the distal portion (20) of the needle hub (4) so that the collar is rotatable about needle hub [0033], and the step of fitting a needle sheath (12) having a second engagement mechanism (90) at its circumferential outer surface to the collar, with the first and second engage mechanisms (68, 90) fitting to each other so that the sheath is removably engaged to the collar to cover the needle that extends from the needle hub, and yet with only one side of the proximal portion of the needle sheath

being engaged to the collar without the needle sheath contacting the needle hub (Figs. 1-10, 12) [0038].

For the method claim, similar to the safety apparatus set forth in claim 1, the needle sheath is fitted to the collar in such a way that only one side of the proximal portion of the needle sheath is engaged to the collar without the needle sheath coming into contact with the needle hub, per shown in Fig. 4.

The instant invention therefore is directed to the way in which a needle sheath engages a collar that is rotatable about a needle hub.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 1-2, 4, 9, 20-21, 23 and 28 stand rejected under 35 U.S.C. §102(e) as being anticipated by Crawford et al. (US 2002/0161336).

II. Claims 8 and 27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Crawford in view of Landis (US 5,490,841).

III. Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Crawford in view of Gyure (US 5,669,889).

IV. Claims 5 and 27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Crawford in view of Johnson et al. (US 2002/0010433).

V. Claims 6 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Crawford in view Pressly, Sr. et al. (US 7,014,622).

VI. Claims 11, 13-17 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson view of Crawford and further in view of Pressly.

VII. Claim 18 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson in view of Crawford, Pressly and Landis.

ARGUMENT

Appellants respectfully request that the patentablilty of all claims discussed hereinbelow be adjudged separately.

I. 35 U.S.C. §102(e) rejection of Claims 1-2, 4, 9, 20-21, 23 and 28 as being anticipated by Crawford et al. (US 2002/0161336)

As noted above in the Summary of the Claimed Subject Matter section, the instant invention relates to a safety needle device, and a method for making it, that has a collar rotatably mounted to a needle hub and a needle sheath that fits to the collar in such a way that it only contacts the collar but not the needle hub for protecting the needle that extends from the needle hub. The way in which the sheath is attached to the collar is by means of a first engage mechanism at the collar coacting with a second engage mechanism at the needle sheath.

Independent Claims 1 and 20

Among other limitations, independent apparatus Claim 1 recites *a collar rotatably mounted directly on the distal portion of the needle hub so as to be rotatable about said needle hub* and independent method Claim 20 recites *rotatably mounting said collar directly on the distal portion of said needle hub so that said collar is rotatable about said needle hub*. Claims 1 and 20 moreover each require that the first and second engage mechanisms at the collar and needle sheath, respectively, be fitted to each other when the sheath is fitted to the collar, and that *only one side of the proximal portion of the sheath be in contact engagement with the collar* (Claim 1), or that *only one side of the proximal portion of the sheath be engaged to the collar* (Claim 20).

Dependent Claims 4 and 23

Claim 4 depends from Claim 1 and Claim 23 depends from Claim 20. Each of these claims defines the second engage mechanism of the needle sheath to be *a groove (90) formed circumferentially proximate to the open end of the needle sheath* and the first engage mechanism of said collar to be *a rib (68) circumferentially formed at the inner wall of the distal end of said collar*, and that the needle sheath is attached to the collar when the rib mates with the groove (Fig. 4) [0038].

Rejection

The examiner asserts that every limitations recited in the above discussed independent Claims 1 and 20, and dependent Claims 4 and 23, is met by Crawford (page 2 of Office Action dated August 24, 2007).

Discussion

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." ... "The identical invention must be shown in as complete detail as is contained in the ,,, claim." MPEP 2131.

Crawford discloses a needle assembly that is assembled from a number of components. These components are: a needle hub 60 for a double ended needle (42, 44), a collar 90 having a rear skirt portion 94 into which the needle hub is fitted, a housing 140 that is pivotally attached to the collar, and a sleeve 50 that is removably threaded into the forward skirt portion 92 of the collar. See Crawford Fig. 2 (overall view of the components), Fig. 4 (collar 90), Fig. 5 (hub 60 with the double ended needle 42, 44), and Fig. 10 (cross sectional view of hub 60 fitted into collar 90) as reproduced hereinbelow.

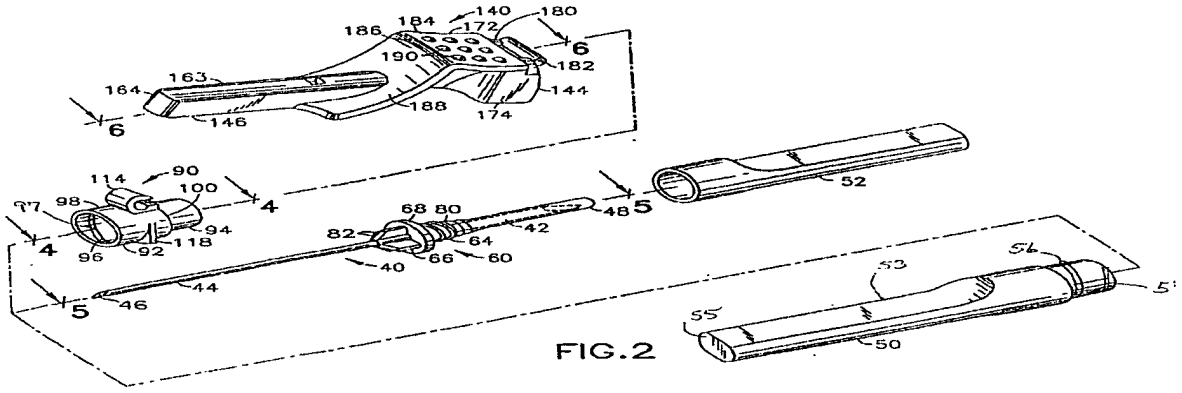

FIG.2

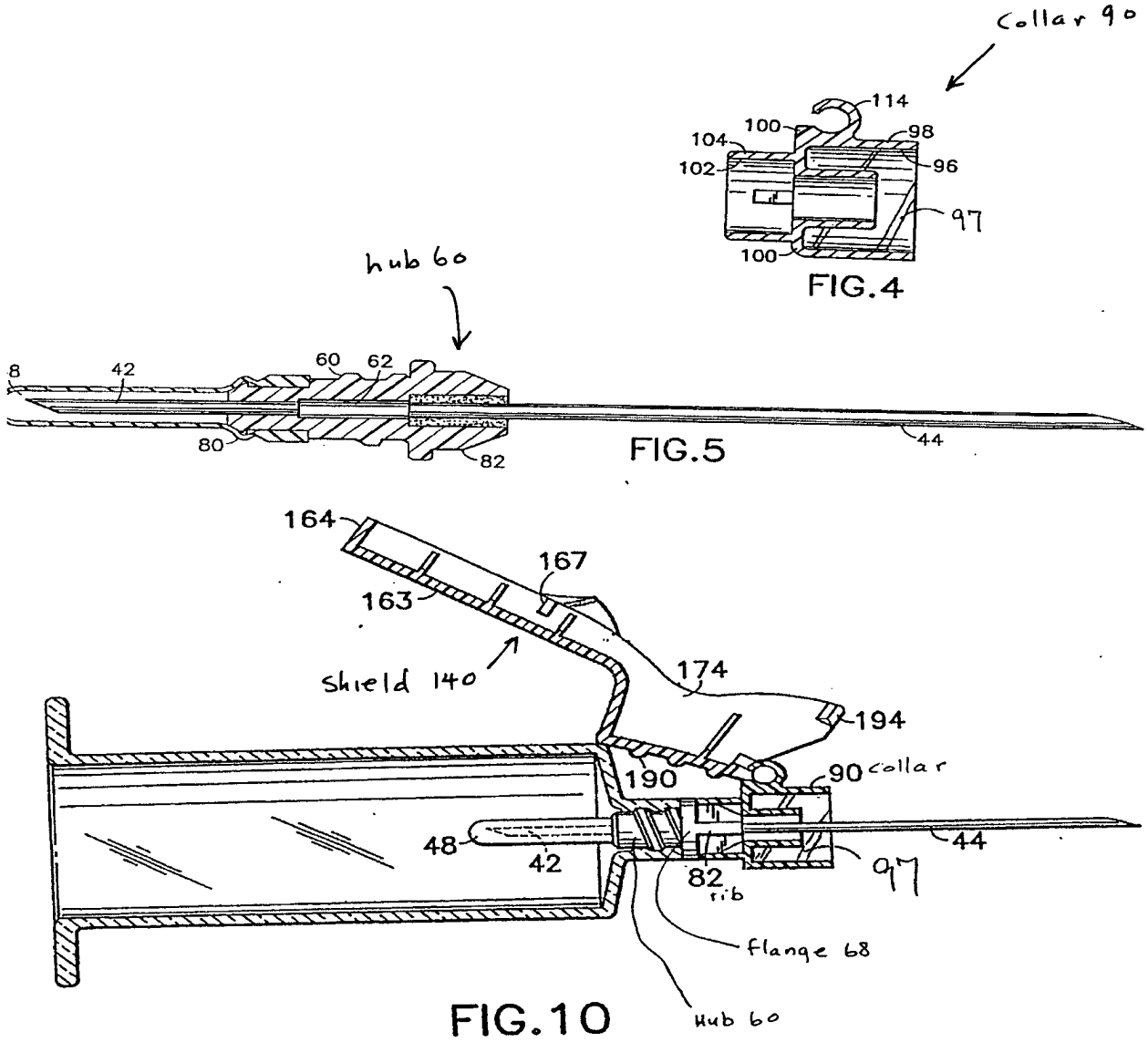

FIG.4

FIG.5

FIG.10

As shown, needle hub 60 and collar 90 are fixedly attached to each other. Such fixed attachment of collar 90 to needle hub 60 is required, and indeed is an essential feature of Crawford, since Crawford requires that the orientation of the shield 140, which is hingedly attached to collar 90 by means of hook 115, be oriented in such a way that the bevel 46 of needle 44 that extends from needle hub 60 be at a given orientation. This is disclosed in paragraph [0064] of Crawford where he states:

> The safety shield assembly and the needle assembly are assembled together whereby needle 40 is connected to hub 60 and sealed with adhesive at the ends of the hub. Hub 60 then is joined with collar 90 by ultra-sonic welding techniques or any other bonding techniques, or mechanical fit, whereby rearward annular skirt 94 of collar 90 mates with ribbed end 66 of the hub. Male ribs 82 of the hub are *contained or forced fitted* within inner sidewall 102 of rearward annular skirt 94 of collar 90. *Collar 90 is aligned with the intravenous end of needle 40 whereby the hook 114 is aligned with the bevel [up] of needle 40*. External threads 96 adjacent proximal end 54 of first rigid sleeve 50 then are threaded into engagement with internal threads 97 formed on inner circumferential surface 96 of forward skirt 92 of collar 90 to cover needle 40.

That collar 90 is fixedly attached to hub 60 is apparent insofar as sleeve 50 has to be rotated relative to collar 90, so that its proximal end 54 could be threaded to the forward skirt 92 of collar 90, by the respective threading of external thread 56 of sleeve 50 to the internal thread 97 of collar 90. In other words, if collar 90 were to be rotatable about needle hub 60, then sleeve 50 would not be able to be threaded into collar 90, as collar 90 would not remain stationary as sleeve 50 is turned. But this is not what is taught by Crawford.

According to the examiner, Crawford "states that the collar may be mounted to the needle hub via mechanical fit and wherein it is the examiner's position that the collar is still fully capable of being rotated about the needle hub since it does not necessarily have to be welded or bonded onto the device." Page 6 of August 24, 2007 Office Action.

The statement that the examiner relied upon in Crawford for her assertion is actually as quoted above: "Hub 60 then is joined with collar 90 by ultra-sonic welding techniques or any other bonding techniques or mechanical fit, whereby rearward annular skirt 94 of collar 90 mates with ribbed end 66 of the hub." [Second sentence of paragraph 0064.]

Appellants respectfully submit that the examiner's reliance of the words "mechanical fit" for asserting that collar 90 is rotatable about needle hub 60 is misplaced, for in the very next sentence as shown above in paragraph [0064] Crawford states: "Male ribs 82 of the hub are contained or force fitted within inner sidewall 102 of rearward annular skirt 94 of collar 90." This sentence makes it clear that the needle hub and the collar of the Crawford

device are not to be rotatable, due to the parts being contained or force fitted. To a person skilled in the art, it would mean that there is no relative rotation between the two parts. In fact, in lines 9-11 of [paragraph 0064], Crawford explains that the bevel of the needle 40 has to be aligned relative to the hook 114 (where needle protection shield 140 is hingedly held) on collar 90 per the following: "Collar 90 is aligned with the intravenous end of needle 40 whereby the hook 114 is aligned with the bevel [tip] of needle 40." This is needed so that the user can see how the needle enters into the patient. Were collar 90 to be rotatable relative to needle hub 60, then the bevel tip of the needle would not be in alignment with hook 114. This would defeat the purpose of the Crawford device. Indeed, there is no disclosure in Crawford that suggests that collar 90 and needle hub 60 are rotatable relative to each other. If anything, the teachings of Crawford indicate otherwise, i.e., that collar 90 is fixedly mounted to needle hub 60.

Moreover, common sense dictates that if collar 90 and needle hub 60 are not fixedly attached, then needle hub 60 (along with the double ended needle fitted thereinto) would potentially fall out of collar 90, for in order for collar 90 to be rotatable about needle hub 60, there must be some clearance, or at most minimal frictional contact, between the outer circumferential surface of the hub 60 and the inner circumferential surface of collar 90 where collar 90 fits over needle hub 60. Yet as clearly shown in Fig. 10, and disclosed per noted above, the ribs 82 are tightly fitted, if not bonded , to the inner circumferential surface 102 (Fig. 5) of the rearward annular skirt 94 of collar 90.

Thus, collar 90 has to be fixedly attached to needle hub 60 not only for the alignment of the tip 60 of needle 40 with shield 90, but also for the bonding or force fitting of protective sleeve 50 to collar 90 to protect needle 40 prior to use. This in addition to the above-noted need for collar 90 to be fixed to hub 60 so that sleeve 50 may be threadedly mated to collar 90.

The instant invention, in contrast, has a collar that is rotatably mounted onto and rotatable about the needle hub.

In fact, Crawford considers the combination of collar 90 and needle hub 60 to be a "needle hub" per se. This is disclosed for example in the Abstract where Crawford discloses "An IV shield is threadedly engaged with the distal end of the hub and protectively covers the piercing element. A hinged shield is hingedly mounted to the hub..." That hub 60 and

collar 90 are considered together as a single hub (due to its welding, bonding or mechanical fit) is further taught by Crawford in his claims wherein each of the independent claims 1, 14 and 15 recites that an IV shield is threadedly engaged with the distal end of the hub. Also, claim 1 specifically recites "a protective cap removably mounted to said proximal end of said hub." Thus, Crawford also teaches that his hub is in contact with the needle sheath 50. Not so with the instant invention which requires that the sheath not be in contact with the needle hub and also have one side in contact engagement to the collar.

The examiner asserts that the "helical thread and corresponding thread" of the Crawford device is a rib and circumferential groove. The examiner further asserts that "[d]ue to the lack of definition of the terms in the specification, it is the examiner's position that under the broadest reasonable interpretation the helical thread and groove is circumferential groove and rib." Last paragraph on page 6 of August 24, 2007 Office Action.

Appellants respectfully submit that the definition of the terms "circumferential groove" and "circumferential rib" are fully explained and shown in the specification of the instant application. For example, the cross sectional view of Fig. 4, the end plan view of Fig. 11, and the perspective views of Figs. 8 and 10 each show clearly the circumferential rib 68 at the distal end of collar 6. The "circumferential groove at sheath 12 is clearly shown in the cross sectional view of Fig. 4 and the perspective views of the sheath 12 at Figs. 12 and 13. Appellants respectfully submit that the illustrations in the noted drawings when coupled with the disclosure in paragraph [0038] provide more than sufficient explanation on what the terms "circumferential rib" and "circumferential groove" mean.

Simply put, the helical thread 56 at sleeve 50 and the counter helical groove 97 at collar 90 of the Crawford device are not the same as a circumferential rib or a circumferential groove. By definition, the helical thread and its corresponding groove are mated by turning whereas a circumferential groove and its corresponding circumferential rib could only be mated by being snapped together, per taught in the disclosure of the instant application. This is conventional if not basic mechanical engineering definition. The interpretation by the examiner is plain unreasonable.

Nor could Crawford anticipate dependent Claim 4 and Claim 23, insofar as each of those claims recites *a groove formed circumferentially at the open end of the needle sheath* and *a rib formed circumferentially at the inner wall of the distal end of the collar*. At best,

Crawford shows forming of helical thread 56 and counter helical groove 97 along corresponding portions of the sheath and collar. A circumferential groove formed at the open end of the sheath and a circumferential rib formed at the inner wall at the distal end are not the same as the helical thread 97 that is formed throughout the forward skirt 92 of collar 90 and the counterbore helical groove 56 that is formed all along the proximal end 54 of sleeve 50 in the Crawford device. See Figs. 2, 4 and 10 of Crawford.

Accordingly, Appellants respectfully submit that the anticipation rejection of independent Claims 1 and 20 and dependent Claims 4 and 23 under Crawford is without merit and not sustainable.

II. §103 rejection of dependent Claims 8 and 27 over the combination of Crawford and Landis (US 5,490,841)

For the §103 rejection of Claim 8 and Claim 27 over the combination of Crawford and Landis (US 5,490,841), it is respectfully submitted that Landis fails to teach lips being *angled toward the interior of housing with the respective angles of said lips being varied along the length of said housing to effect guide for said needle to smoothly enter into said housing at an angle through said opening*, as required in claims 8 and 27. Such can readily be seen by comparing the angled slot opening 88 shown in Fig. 10 of the instant application with Figs. 6-12 of the protective housing shown in Landis.

Claims 8 and 27 are therefore respectfully submitted to be patentable over the prior art.

III. §103 rejection of Claim 10 over Crawford and Gyure et al, (US 5,669,889)

Appellants submit that Claim 10 stands or falls with independent Claim 1 from which it indirectly depends.

IV. §103 rejection of dependent Claims 5 and 24 over Crawford and Johnson et al. (US 2002/0010433)

Claim 5 depends from independent Claim 1, while Claim 24 depends from independent Claim 20. Each of Claims 5 and 24 defines the needle hub (4) to have a luer end (40) at its proximal portion and a user graspable ring (28) surrounding and in spaced relationship with the needle hub, with the ring being integral of the needle hub via a distal end wall (30) extending transversely from the needle hub (Figs. 6 and 7) [0029-0030].

In *KSR International Co. v. Teleflex Inc.*, (No. 04/1350, decided April 30, 2007), the Supreme Court holds that "the combination of familiar elements according to known methods is likely to be obvious when it does no more yield predictable results." Page 12 of slip opinion. The court further holds that whether an improvement is obvious depends on "the predictable use of prior art elements according to the established functions" (page 13).

In light of the Court's mandate, it is believed that the question that should be addressed by the Board in determining whether the instant invention, as set forth in Claims 5 and 24, is patentable over the combination of Crawford and Johnson is to look at whether or not the claimed invention, to a person skilled in the art, would have been predictably resulted from the Crawford/Johnson combination.

Appellants respectfully submit that the combination of Crawford and Johnson, assume feasible for the sake of argument, produces a predictable result that has no bearing to the claimed subject matter per the following.

Johnson discloses an adapter 40 for a "LUER LOK" receptacle to prevent crack and break at the intersection of the hub with a syringe barrel (Fig. 1C and paragraph 0008 of Johnson]. The Johnson adapter has a housing 42 that surrounds the male end 70 of a fitting 44 of a catheter 46 (Fig. 2C), so that a recess 50 is formed between housing 42 and male connector end 70. In operation, the adapter 70 is press fitted to a hub 18 that extends from the barrel 14 of a syringe [0004] to form a "rigidifying seal" to prevent the hub 18 from spreading, to decrease the likelihood that receptacle 12 of the syringe would break or crack, and to provide a fluid tight seal to prevent fluid or vacuum leak from the syringe/adapter junction [Fig. 2D, paragraph 0044].

Thus, the hub that is disclosed in Johnson is *a syringe hub* to which, at best, a needle assembly may be mated. It is not the *needle hub* to which a needle assembly is mated per required in the claims of the instant invention. Further, that Johnson discloses

the syringe hub to be press fitted to his adapter for "rigidifying" the syringe hub suggests that the Johnson adapter is not rotatably mounted onto the syringe hub. That being the case, there is no conceivable way in which the instant invention, which requires that *the ring be integral of the needle hub via a distal end wall that extends from the needle hub*, could predictably result from the combined teachings of Crawford and Johnson, per asserted by the examiner.

Appellants therefore respectfully submit that the rejection of Claims 5 and 24 under the combination of Crawford and Johnson is without merit and not sustainable.

V. §103 rejection of dependent Claims 6 and 25 over Crawford and Pressly, Sr et al. (US 7,014,622)

Claims 6 and 25 depend from Claims 5 and 24, respectively.[3]

In support of this rejection, the examiner asserts that Pressly "teaches the use of a window as a transparent ring on a needle assembly for viewing a joint of a needle hub, see figure 10 and col. 7 lines 35-43, wherein the transparency would be deemed a window." 2nd full paragraph on page 4 of the August 24, 2007 Office Action.

In addition to the discussion in Section IV above showing that Crawford and Johnson cannot be combined as asserted by the examiner, and therefore by that alone the rejection of Claims 6 and 25 cannot stand, Appellants further submit that Pressly does not disclose any window "transparent ring." Rather, as shown in Fig. 10 and the isolated sectional view of the guard edge of the needle guard in Fig. 10A, Pressly discloses a transparent needle assembly 8 that is to be fitted to the syringe barrel 6 for enclosing the needle hub 2 during the manufacturing process of the Pressly device. See Fig. 1 for the cross sectional view of the assembled Pressly safety syringe. With the needle assembly 8 being transparent, the user can see the joining of the head 12 of the needle 14 to the needle hub 2 (col. 7, lines 35-47).

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[3] Appellants believe that the examiner has failed to properly reject Claims 6 and 25 insofar as those claims respectively depend from dependent Claims 5 and 24, which stand rejected under Crawford and Johnson. Thus, the proper rejection for Claims is believed to be Crawford in combination with Johnson and further in view of Pressly.

Thus, in contrast to the assertion by the examiner, the Pressly needle assembly 8, be it transparent or otherwise, is not a ring that is in spaced relationship with a luer connector. There in fact is no luer connector disclosed in Pressly, for the Pressly device is a syringe with a specially designed needle hub that is adapted to have different types of needles connected thereto (column 5, lines 29-35). Indeed, Pressly discloses that needle assembly 8 is permenanty joined to syringe barrel 6 (column 5, lines 59-63). Thus, to assert that the syringe of Pressly may be combined with the double-ended needle of Crawford and further the adapter for a luer lock as disclosed in Johnson does not make any sense, let alone providing the predictable result required for a valid obviousness rejection per mandated by the KSR holding noted above.

Appellants therefore respectfully submit that the rejection of those Claims 6 and 25 is without merit and not sustainable.

VI. §103 rejection of Claims 11, 13-17 and 19 over Crawford et al. (US 2002/0161336) and Johnson et al. (US 2002/0010433)

Independent Claim 11

Claim 11 sets forth a combination comprising a needle hub that has a luer connector at its proximal portion and a ring surrounding but in spaced relationship with the luer connector. At least one window is provided at the ring to enable viewing of the luer connector. A collar having a housing pivotally connected thereto is rotatably fitted about the distal portion of said needle hub. A needle sheath is fitted to the collar but with only one side in contact engagement to said collar.

This rejection is based on the same prior art applied against Claims 5 and 24 in Section IV above. Accordingly, the same argument set forth in Section IV for patentability is equally applicable herein. In addition, given that the "window" feature in the ring is recited in Claims 6 and 25 and discussed in Section V above, the argument in Section V relating to Crawford and Johnson is equally applicable herein.

In brief, neither Crawford nor Johnson discloses a "window " at a ring that spatially surrounds a luer end.

Moreover, Crawford discloses a needle hub 60 that is fixed to a collar 90. The crux of the Johnson invention is the forming of a rigidifying seal to support the outside diameter of hub 18 so as to prevent hub 18 from spreading and/or from cracking or breaking, and also allow the user to "manipulate more aggressively" the device. In addition, the housing 42 provides for a fluid tight seal to prevent fluid from leaking [0044]. That housing 42 forms a rigidified seal clearly means that Johnson does not intend to have any "window" or openings provided at housing 42. Otherwise, the purpose of the Johnson adapter being a rigidifying seal would be totally defeated, because a "window" would de-rigidify hub 18 and also allow fluid to escape from the adapter.

Further more, as discussed above, the combination of Crawford and Johnson does not pass muster under the predictable result analysis mandated by the KSR decision for validation of an obviousness rejection.

The rejection of Claim 11 is therefore respectfully submitted to be without merit and not sustainable.

Dependent Claims 13-17 and 19

Claim 13 depends from Claim 11 and defines the needle sheath (12) to have a first engage mechanism (90) proximate to its open end and the collar (4) to have a second engage mechanism (68) at its distal portion (Figs. 1-10 and 12) [0038].

Claim 14 depends from Claim 11 and defines the needle sheath (12) to have a circumferential groove (90) proximate to its open end and the collar (4) to have a second engage mechanism (68) at its distal portion.

To rebut the rejection of Claims 13 and 14, the same argument set forth above in Section I for Claims 4 and 23 is equally applicable herein.

Claim 15 depends from Claim 11 and defines the ring to include at least one window (92) on its sidewall to enable viewing of the luer connector and the proximal portion of the needle hub [0035].

There is no disclosure or suggestion in either Crawford or Johnson of a window formed at the side wall of the ring that enables the viewing of both the luer connector and the proximal portion of the needle hub.

Claim 17 depends from Claim 11 and defines the needle hub to include a plurality of flanges (44) extending from its distal portion that are located a predetermined distance from a wall (30) projecting orthogonally from said needle hub (4), so as to define a space (52) between the flanges and the wall circumferentially about the needle hub (Fig. 7) [0031]. The collar is defined to include a plurality of protrusions (62) at the inner wall of its proximal portion (58), with the protrusions dimensioned to fit to the space when the collar is mated to the needle hub, so that the collar is rotatable about said needle hub (Figs. 3-5) [0033].

Given that Claims 7 and 26 are deemed to contain allowable subject matter and Claim 17 covers similar subject matter, Appellants respectfully submit that Claim 17 should likewise be allowed. Crawford and Johnson, either singly or in combination, simply fail to disclose or suggest any of the subject matter recited in Claim 17.

VII. §103 rejection of dependent Claim 18 over Crawford and Johnson in combination with Pressly and Landis

Claim 18 recites similar subject matter as Claims 8 and 27. Accordingly, the same argument set forth above in Section II relating to Claims 8 and 27 is equally applicable herein.

In view of the forgoing, Appellants respectfully submit that the rejections of the above-discussed claims are without merit and not sustainable. The Board is therefore respectfully requested to reverse the examiner's rejections.

Respectfully submitted,

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Date: Jan 16, 2008

CLAIMS APPENDIX

1. Safety apparatus, comprising:

a needle hub having a proximal portion and a distal portion, a needle extending from a distal end of said needle hub;

a collar rotatably mounted directly on the distal portion of said needle hub so as to be rotatable about said needle hub, said collar having a first engage mechanism at its inner circumferential surface;

a housing pivotally connected to said collar; and

a needle sheath having a proximal portion with a second engage mechanism at its outer circumferential surface, said first and second engage mechanisms fitted to each other when said sheath is fitted to said collar, said proximal portion having only one side in contact engagement to said collar for covering said needle extending from the distal end of said needle hub and said sheath is not in contact with said needle hub when said sheath is fitted to said collar and said first and second engage mechanisms are engaged to each other.

2. Safety apparatus of claim 1, wherein after said needle sheath is removed from said collar, said housing is pivotable to a position substantially in alignment along a longitudinal axis of said needle hub for covering said needle.

3. (Cancel)

4. Safety apparatus of claim 1, wherein said second engage mechanism of said needle sheath comprises a groove formed circumferentially proximate to the open end of sad needle sheath and wherein said first engage mechanism of said collar comprises a rib circumferentially formed at the inner wall of the distal end of said collar; and

wherein said needle sheath is attached to said collar when said rib of said collar mates with said groove after said needle sheath is positioned over said needle and engages said collar.

5. Safety apparatus of claim 1, wherein said needle hub comprises a luer end at its proximal portion, a ring surrounding and spaced from said luer end, said ring being integral of said needle hub via a distal end wall extending transversely therefrom; and

wherein a user can readily grasp said ring to couple said safety device to a medical device by threadingly mating said luer end of said needle hub to a counterpart luer end at said medical device.

6. Safety apparatus of claim 5, wherein said ring comprises at least one window to enable the user to view said luer end of said needle hub and said needle hub.

7. (Allowable) Safety apparatus of claim 1, wherein said needle hub comprises at least one flange extending from its distal portion, said flange being located a predetermined distance from a wall projecting orthogonally from said needle hub, a space being formed between said flange and said wall circumferentially about said needle hub; and

wherein said collar comprises at least one protrusion at the inner wall of its proximal portion, said protrusion being dimensioned to fit to said space defined between said flange and said wall when said collar is mated to said needle hub, said collar rotatable about said needle hub after matingly fitted to said space.

8. Safety apparatus of claim 1, wherein said housing comprises a longitudinal opening formed by first and second lips each extending along substantially the length of said housing, said first lip overlapping a portion of said second lip with said opening being off centered from said longitudinal axis, each of said lips being angled toward the interior of said housing with the respective angles of said lips being varied along the length of said housing to effect a guide for said needle to smoothly enter into said housing at an angle through said opening when said housing is pivoted to cover said needle, said needle not removable from said housing once said needle fully enters into said housing.

9. Safety apparatus of claim 1, wherein said collar has formed proximate to its distal end one lock mechanism and wherein said housing has formed at its proximal end an other lock mechanism, said one and other lock mechanisms coacting to fixedly retain said housing to said collar once said housing is pivoted to a position in substantial alignment with said needle hub to cover said needle.

10. Safety apparatus of claim 9, wherein said one lock mechanism comprises at least one one way catch member extending from the outer surface of said collar or said housing, and said other lock mechanism comprises at least one corresponding aperture at said housing or said collar, said one way catch member matingly coupled to said aperture for fixedly retaining said housing to said collar when said housing is pivoted to cover said needle.

11. In combination, a needle hub having a proximal portion and a distal portion, said proximal portion having a luer connector and a ring surrounding but in spaced relationship with said luer connector, at least one window provided at said ring to enable viewing of said luer connector, said ring being graspable by a user to remove said needle hub from a syringe, said distal portion of said needle hub having a distal end from which a needle extends, a collar having a housing pivotally connected thereto directly fitted to and rotatable about said distal portion of said needle hub, and a needle sheath having a proximal portion with only one side in contact engagement to said collar, said needle sheath not in contact with said needle hub and removable from said collar to expose said needle for use.

12. (Canceled)

13. Combination of claim 11, wherein said needle sheath comprises a first engage mechanism proximate to its open end and wherein said collar comprises a second engage mechanism at its distal portion, said first engage mechanism engages said second engage mechanism for attaching said needle sheath to said collar when said needle sheath is positioned over said needle and mates with said collar.

14. Combination of claim 11, wherein said needle sheath comprises a circumferential groove proximate to its open end and said collar comprises a circumferential rib at its distal portion, said rib mating to said groove when said needle sheath is positioned over said needle and fitted to said collar.

15. Combination of claim 11, wherein said ring comprises at least one window on its sidewall to enable viewing of said luer connector and said proximal portion of said needle hub.

16. Combination of claim 11, wherein said ring is adaptable to be used by a user to grasp said needle hub for connecting said luer connector to a corresponding luer connector of a medical device.

17. Combination of claim 11, wherein said needle hub comprises a plurality of flanges extending from its distal portion, said flanges being located a predetermined distance from a wall projecting orthogonally from said needle hub, a space being defined between said flanges and said wall circumferentially about said needle hub, and wherein said collar comprises a plurality of protrusions at the inner wall of its proximal portion, said protrusions being dimensioned to fit to said space when said collar is mated to said needle hub, said collar rotatable about said needle hub after matingly fitted to said space.

18. Combination of claim 11, wherein said housing comprises a longitudinal opening formed by first and second lips each extending along substantially the length of said housing, said first lip overlapping a portion of said second lip with said opening being off centered from said longitudinal axis, each of said lips being angled toward the interior of said housing with the respective angles of said lips being varied along the length of said housing to effect a guide for said needle to smoothly enter into said housing at an angle through said opening when said housing is pivoted to cover said needle, said needle not removable from said housing once said needle fully enters into said housing.

19. Combination of claim 11, wherein said collar has formed proximate to its distal end a first lock mechanism and wherein said housing has formed at its proximal end a second lock mechanism, said first and second lock mechanisms coacting to fixedly retain said

housing to said collar once said housing is pivoted to a position in substantial alignment with said needle hub to cover said needle.

20. A method of making a needle assembly, comprising the steps of:

a) providing a needle hub having a proximal portion and a distal portion;

b) fixedly attaching a needle to a distal end of said needle hub;

c) pivotally connecting a housing to a collar having a first engage mechanism formed at its inner circumferential surface;

d) rotatably mounting said collar directly on the distal portion of said needle hub so that said collar is rotatable about said needle hub; and

e) fitting a needle sheath having a second engagement mechanism at its circumferential outer surface to said collar, said first and second engage mechanisms fitting to each other so that said sheath is removably engaged to said collar and only one side of a proximal portion of said needle sheath is engaged to said collar without said needle sheath contacting said needle hub for covering said needle extending from the distal end of said needle hub.

21. Method of claim 20, further comprising the steps of:

removing said needle sheath from said collar before using said needle; and

pivoting said housing to a position substantially in alignment along a longitudinal axis of said needle hub for covering said needle.

22. (Canceled)

23. Method of claim 20, wherein said second engage mechanism comprises a circumferential groove formed proximate to an open end of said needle sheath, and wherein said first engage mechanism comprises a rib formed circumferentially at the inner wall of a distal portion of said collar; and

wherein said step e comprises the steps of:

positioning said needle sheath over said needle; and

engaging said needle sheath to said collar until said rib of said collar mates with said groove of said needle sheath.

24. Method of claim 20, wherein said step a comprises the steps of:

forming a luer end at the proximal portion of said needle hub; and

forming a ring in spaced relation to surround said luer end, said ring being integral of said needle hub via a distal end wall;

wherein a user can readily grasp said ring to couple said needle assembly to a medical device by mating said luer end of said needle hub to a counterpart luer end at said medical device.

25. Method of claim 24, wherein said forming a ring step further comprises the step of:

forming at least one window on said ring to enable the user to view said luer end of said needle hub and said needle hub.

26. (Allowable) Method of claim 20, wherein said step a comprises the steps of:

providing at least one flange extending from said distal portion of said needle hub; and

locating said flange a predetermined distance from a wall projecting orthogonally from said needle hub to define a space between said flange and said wall circumferentially about said needle hub;

wherein the method further comprising the steps of:

forming at least one protrusion at the inner wall of said collar;

dimensioning said protrusion to fit to said space defined between said flange and said wall; and

mating said collar to said needle hub, said collar rotatable about said needle hub after being mated to said space.

27. Method of claim 20, further comprising the step of:

providing a longitudinal opening along said housing by forming first and second lips each extending along substantially the length of said housing, said first lip overlapping a portion of said second lip with said opening being off centered from said longitudinal axis, each of said lips being angled toward the interior of said housing with the respective angles of said lips being varied along the length of said housing to effect a guide for said needle to smoothly enter into said housing at an angle through said opening when said housing is pivoted to cover said needle, said needle not removable from said housing once said needle fully enters into said housing.

28. Method of claim 20, further comprising the steps of:

forming a first lock mechanism proximate to the distal end of said collar; and

forming a second lock mechanism at a proximal end of said housing;

wherein said first and second lock mechanisms coact to fixedly retain said housing to said collar once said housing is pivoted to a position in substantial alignment with said needle hub to cover said needle.

DRAWINGS APPENDIX

Figures 1 to 13 (7 sheets) of the instant application are attached.

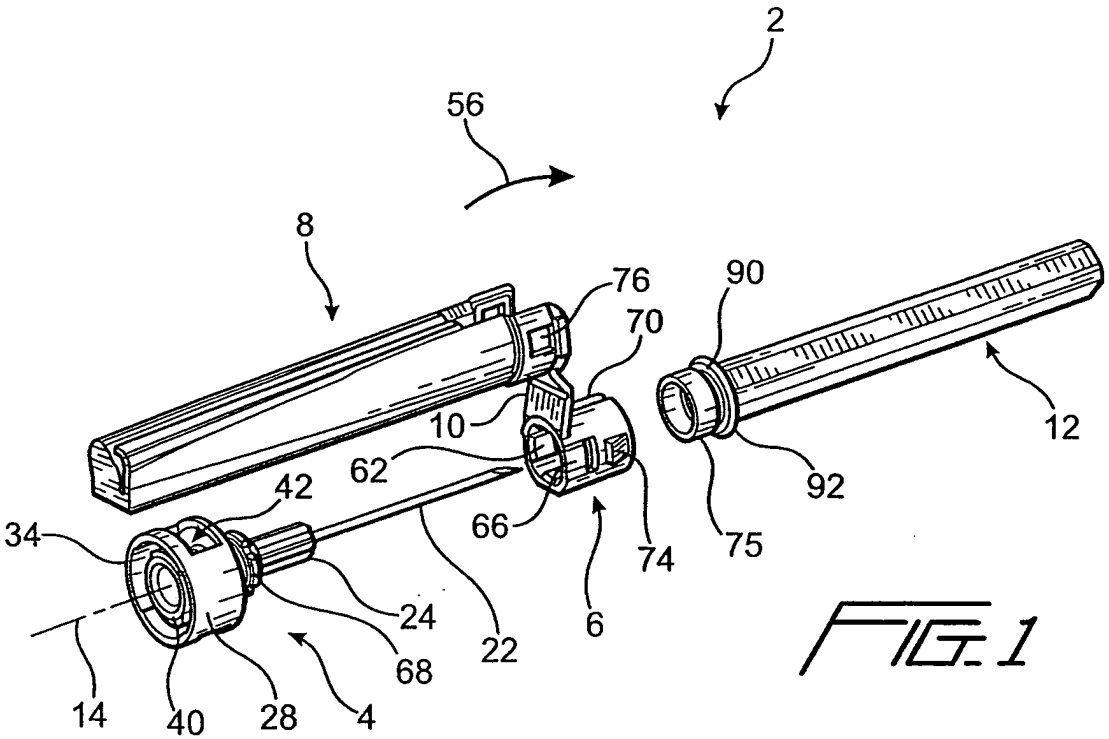
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FIG. 1

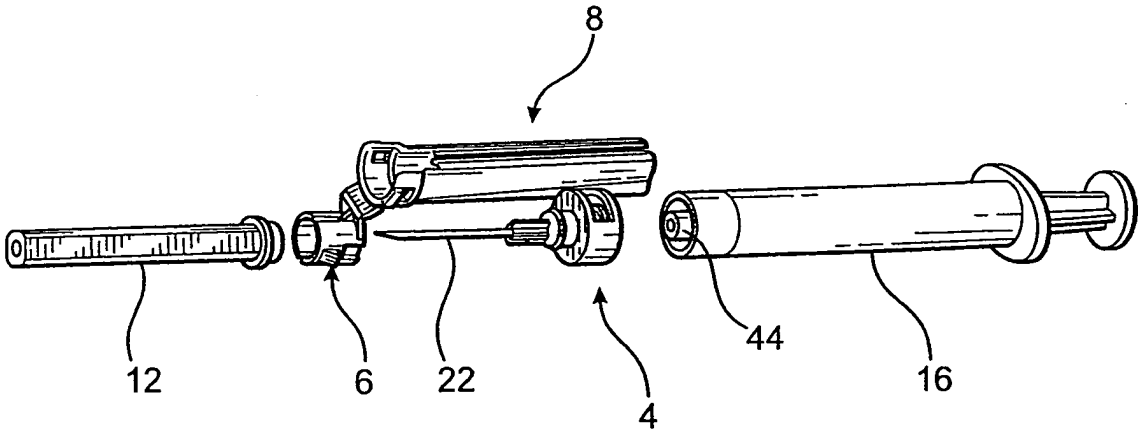
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FIG. 2

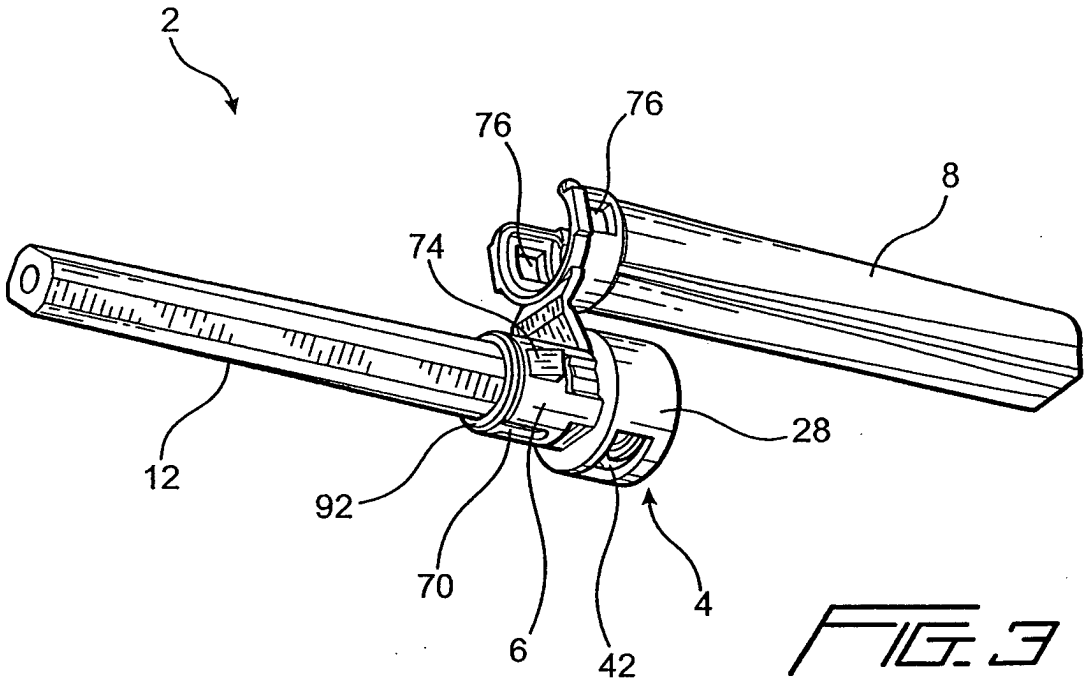

FIG. 3

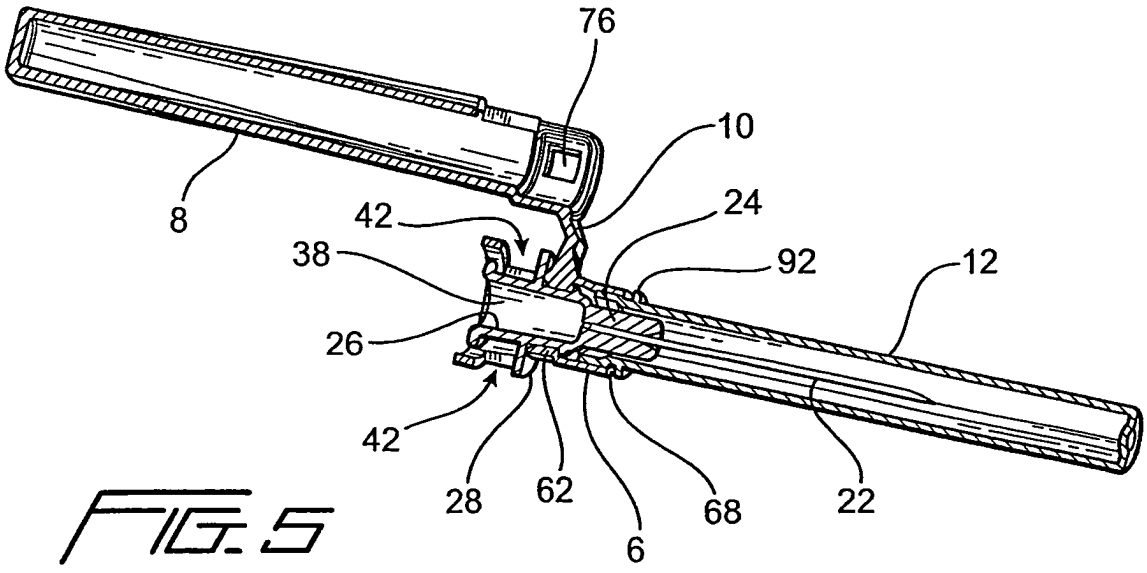

FIG. 5

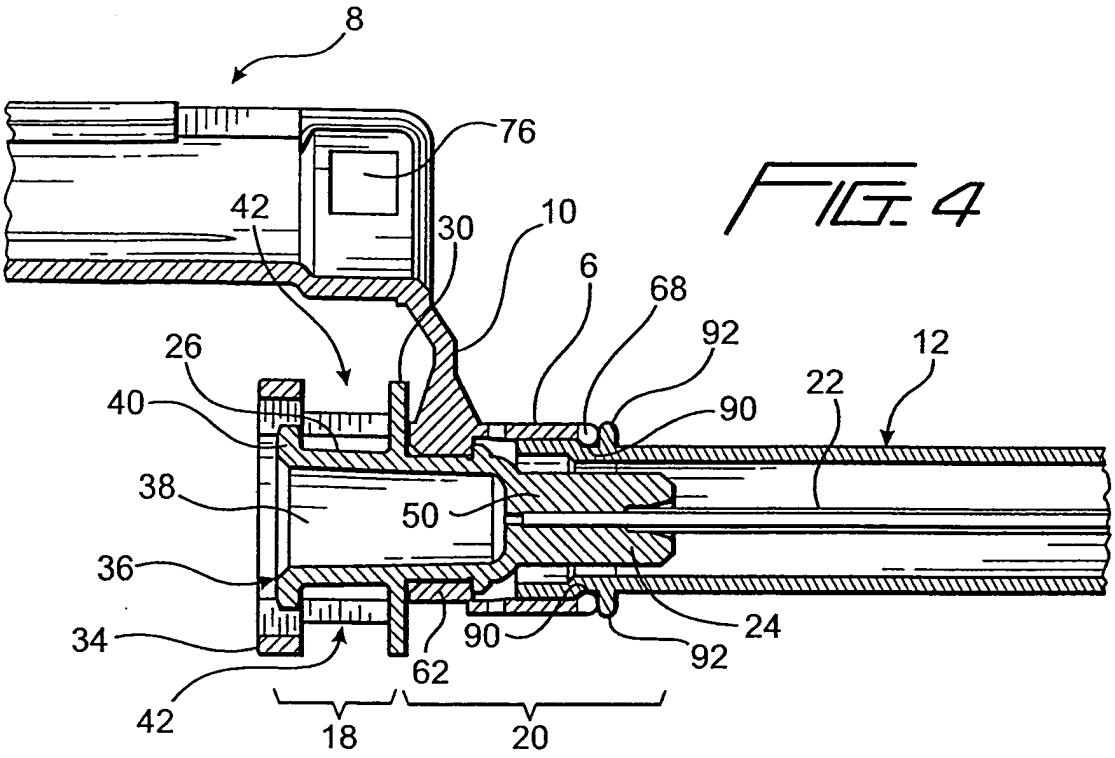
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FIG. 4

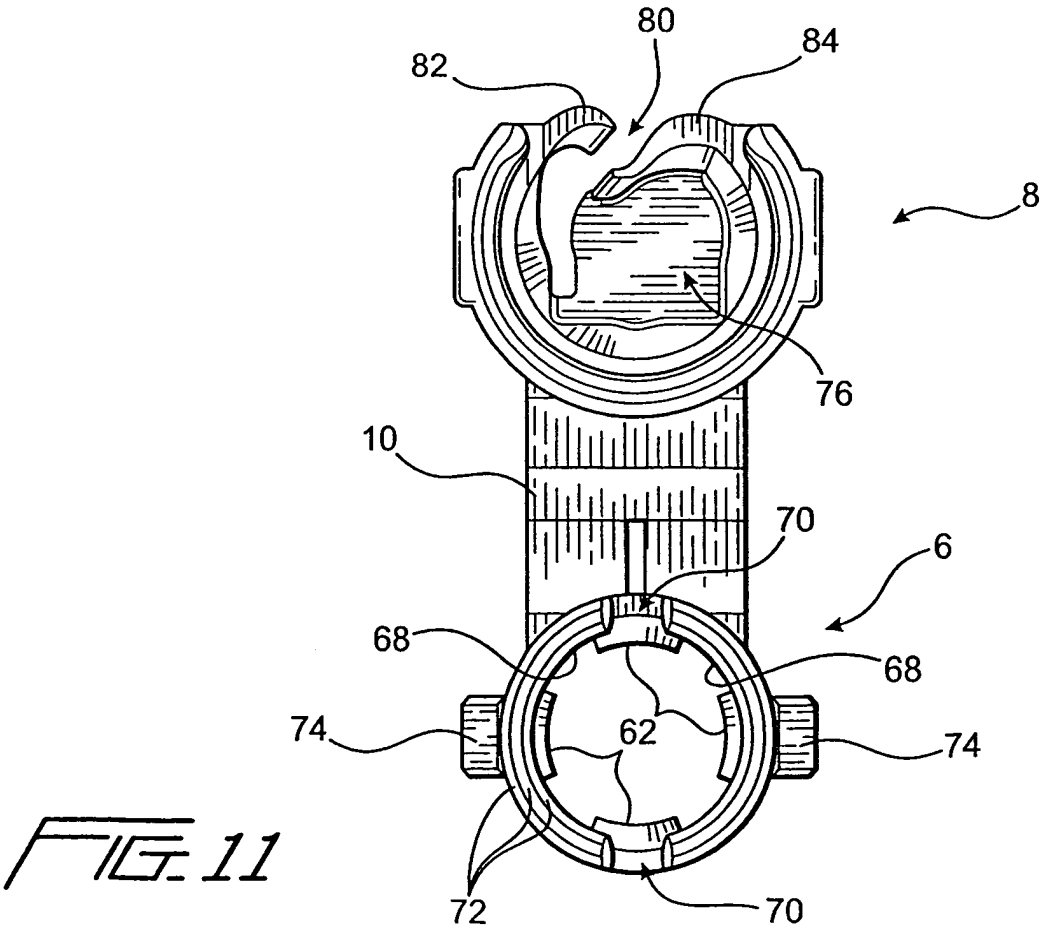
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FIG. 11

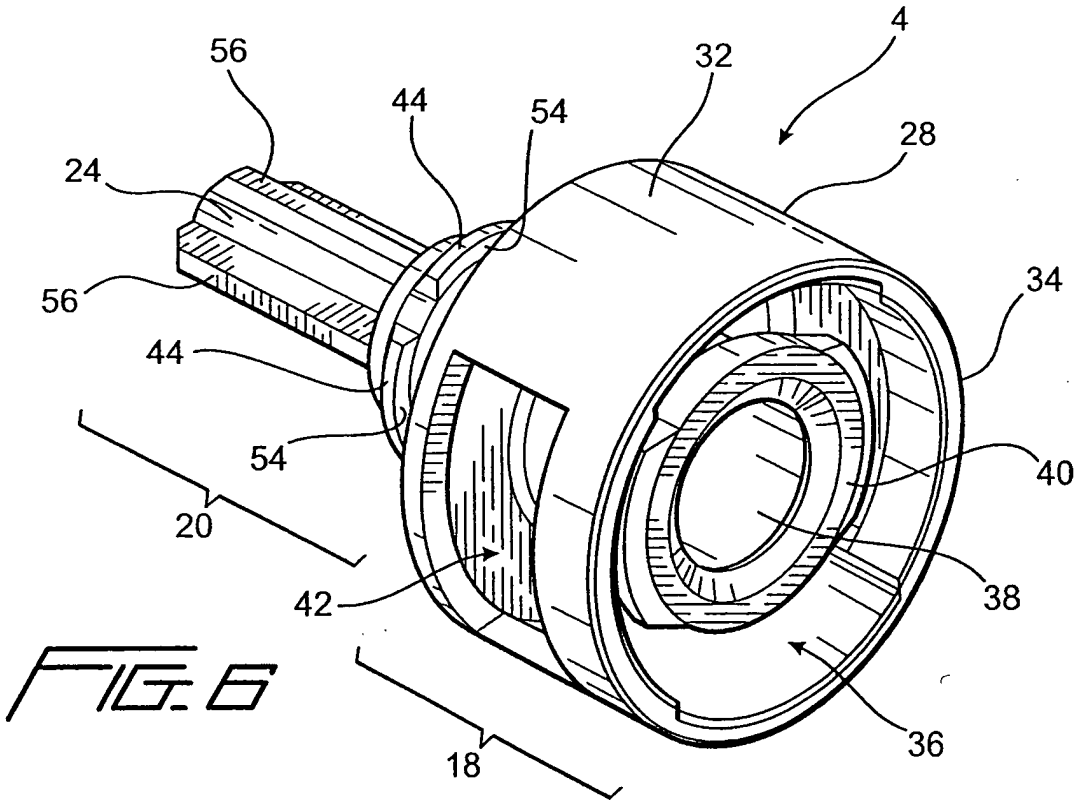
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FIG. 6

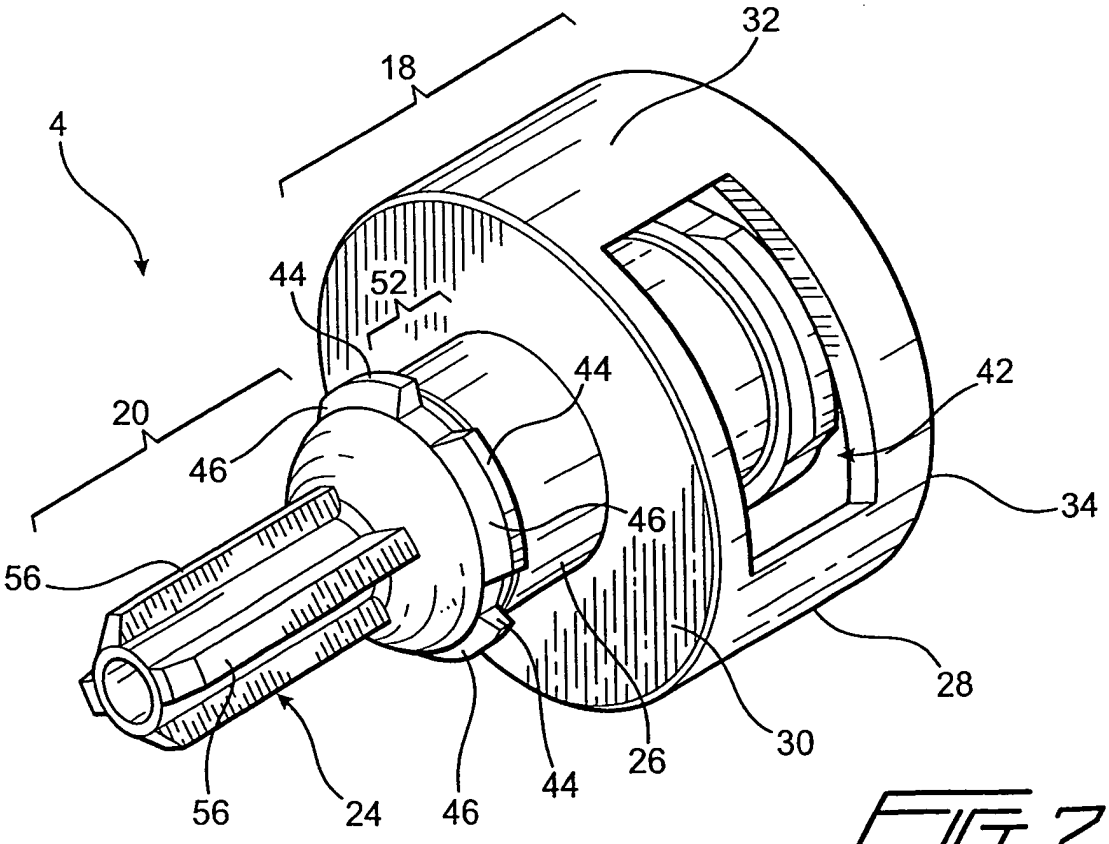
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FIG. 7

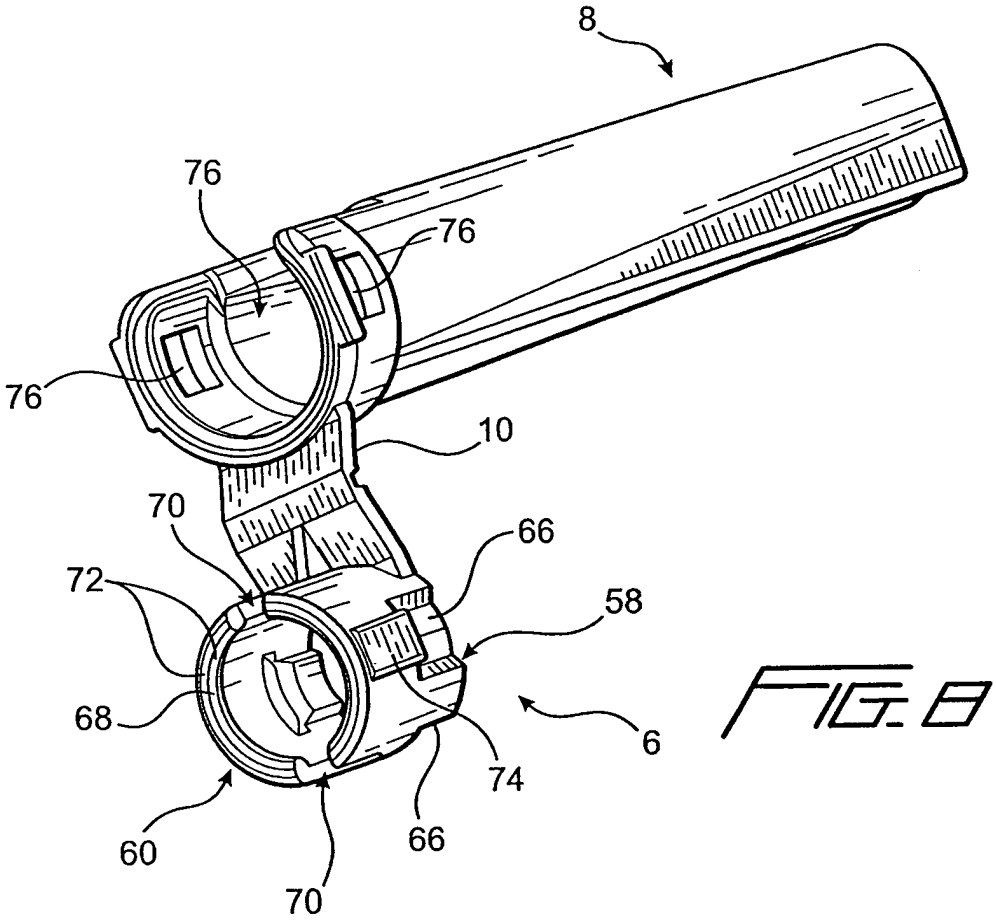
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FIG. 8

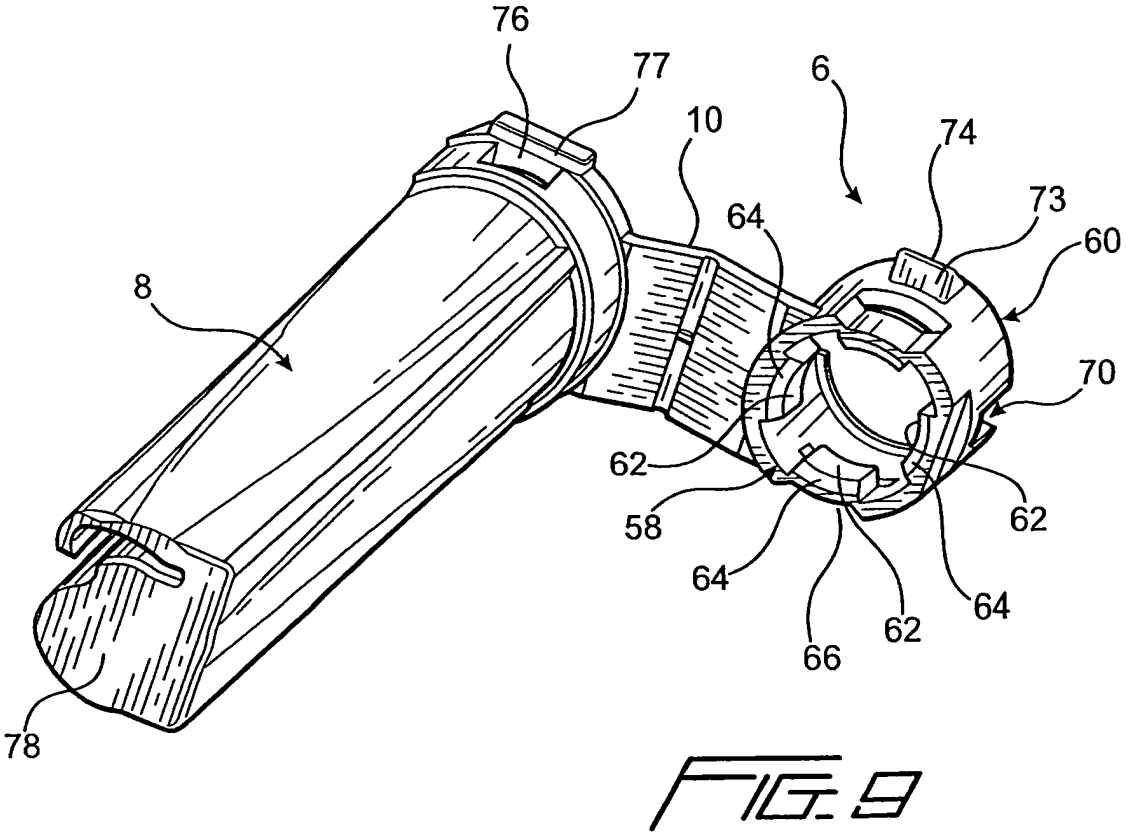
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FIG. 9

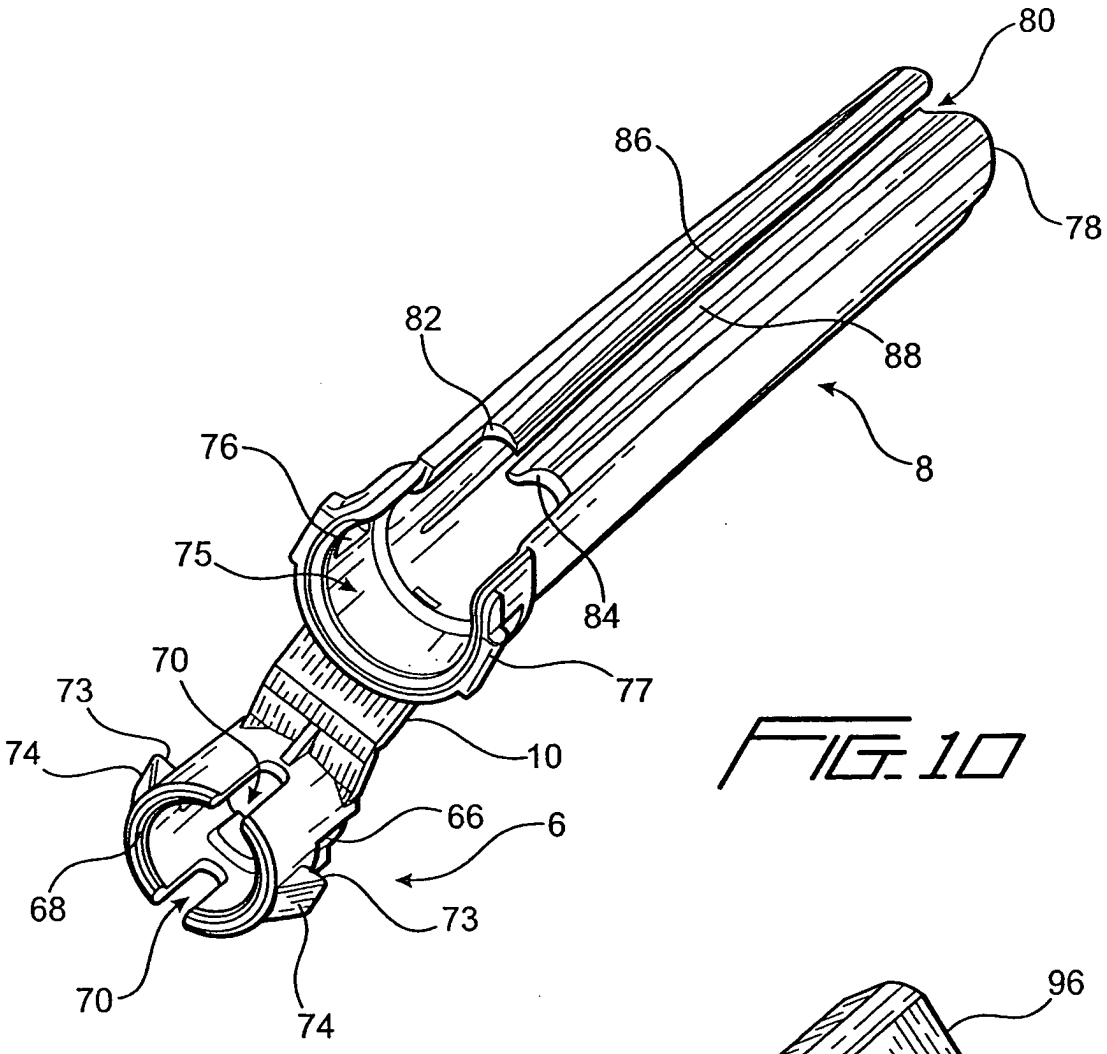
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FIG. 10

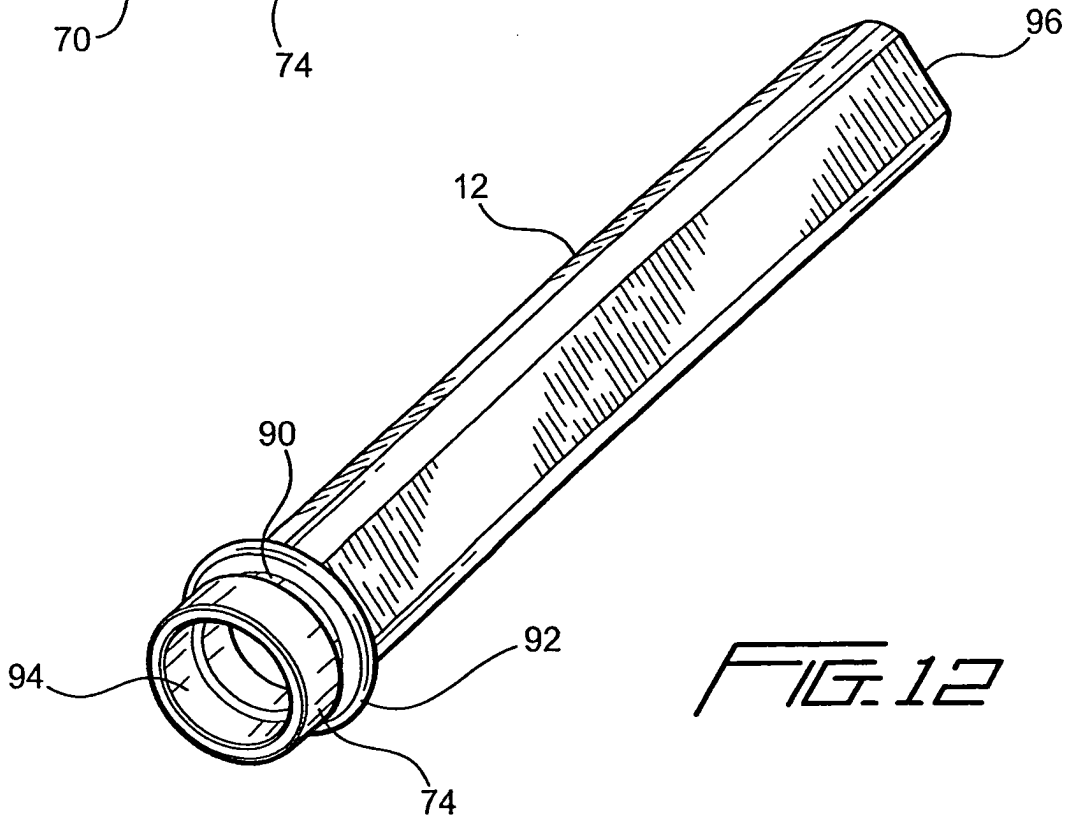
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FIG. 12

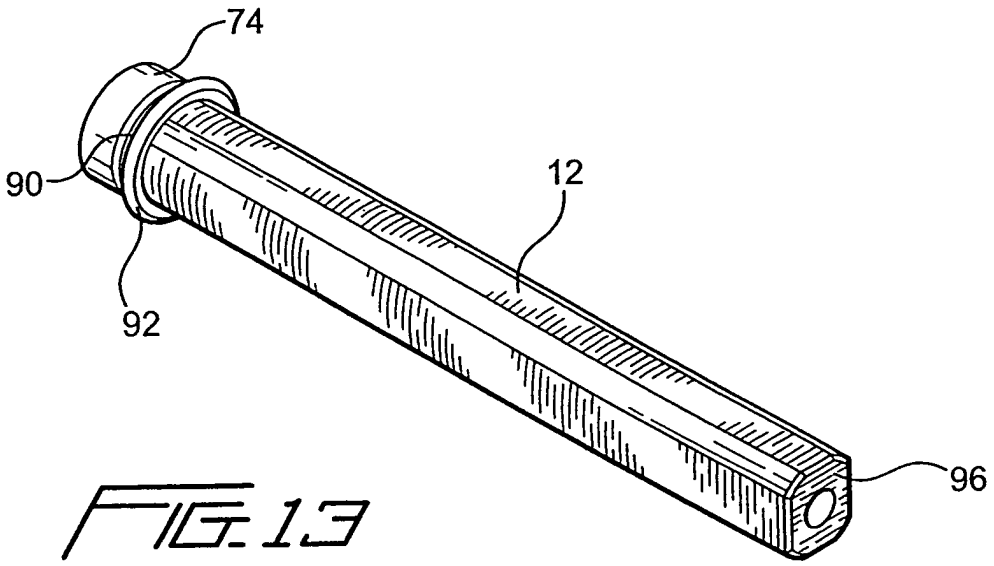

FIG. 13

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.